UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDTECH PRODUCTS, INC., Plaintiff, v. RANIR, LLC and CVS Pharmacy, Inc., Defendants.	07 CV 3302-WP4-LMS (Consolidated)
MEDTECH PRODUCTS, INC., Plaintiff, v. DENTEK ORAL CARE, INC., Defendant.	
MEDTECH PRODUCTS, INC., Plaintiff, v. POWER PRODUCTS, INC., Defendant.	

REPLY OF DEFENDANT DENTEK ORAL CARE, INC. TO PLAINTIFF MEDTECH PRODUCTS INC.'S CLAIM CONSTRUCTION BRIEF

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INTRODUCTION

Medtech Products, Inc.'s ("Medtech") opening brief ("Medtech Br.") is directed to what Plaintiff wishes its invention were rather than what it actually is. At page 2, Medtech informs the Court: "In layman's terms, the subject of the '051 Patent is a dental protector whose primary purpose is to prevent bruxing, *i.e.*, grinding, and clenching, *i.e.*, closing tightly of the teeth. The dental protector is unique in that it may be fitted without the need for a dental professional." Yet, the patent itself expressly contradicts Medtech's claim that a self-fitting device is "unique."

The '051 Patent states that "[i]nterocclusal appliances, such as nightguards, have been long recognized as beneficial for the alleviation of the adverse effects of bruxism and clenching" and that these devices included those fitted by dentists and those that were self-fitted. (Col. 1, ll. 23-28.) Clearly, the inventors did not invent self-fitting nightguards. They sought to improve the fit and durability of a well-known device. The patent leaves no doubt in this regard. (Col. 1 at ll. 43-45.) The fitting problem involved the user's inability to center and align the preform material to take a dental impression. (Col. 1 at ll. 46-52.) The durability problem involved separation of the liner from the base due to shear forces exerted by grinding teeth. (Col. 1, ll. 46-62.)

The inventors' solution was a small step from the close prior art cited by the Patent Examiner. See DenTek's Opening Brief at pp. 8-9. The Summary of the Invention, as well as the Abstract, and the full specification of the '051 patent define it:

SUMMARY OF THE INVENTION

> A self fitting interocclusal appliance includes a base having a generally planar, smooth, occlusal face and a pair of parallel curved side walls. The base is molded of a thermoplastic having a Vicat softening temperature of at least 65º C. and a Shore A hardness of at least 80.
>
> Molded into the base between and above the side walls is an impression preform comprising an EVA copolymer having approximately thirty percent vinyl acetate, a Vicat softening temperature of approximately 36º C. and a Shore A hardness below 80.

> The preform includes a thick footing having a planar upper face and a shallow bight shaped centric relation pilot channel defined by peripheral walls which are sloped downwardly and inwardly from an elevation above the side walls of the base. The upper face of the footing defines the bottom of the pilot channel. (Col 1, l. 65 – Col. 2, l. 13.)

Furthermore, DenTek's interpretation of the invention is not only consistent with the Examiner's stated Reasons For Allowance, it is the only interpretation presented that is consistent with them.

ADDITIONAL LEGAL PRINCIPLES REGARDING CLAIM CONSTRUCTION

A. The Proper Construction Follows From The Stated Problem, The Stated Objectives, The Solution Stated In The Summary Of Invention, And The Examiner's Stated Reasons For Allowance

Medtech devotes pages to a general summary of cases on claim construction, but fails to identify any that bear meaningfully on the present case. Controlling case precedents establish that where, as here, the patent clearly states the problem faced, clearly states the inventors' objective, and clearly states a solution in the Summary of the Invention and Abstract that matches the language of the claim, the correct construction becomes clear. *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1348 (Fed. Cir. 2004) (upon examining the Abstract, Statement of the Invention, other parts of the specification, as well as the prosecution history in supporting defendant's construction of claim language, the court found that the specification "repeatedly and consistently describes the. . .claimed inventions as communicating directly over a telephone line"). This becomes all the more so when it is consistent with, indeed required by, the Examiner's stated Reasons for Allowance in issuing the claim.

The Purpose of the '051 invention

A court's interpretation of a claim phrase should be "consonant with the purpose of the invention." *Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000). Poor fitting and lack of durability were problems the inventors identified with the prior art. (Col. 1, ll. 44-46.)

The Summary of the '051 invention

The Summary of the Invention casts light upon what the patentee has claimed. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1345 (Fed. Cir. 2001). It is a particularly important part of the specification from which to properly determine the scope of a claim term. *See* authorities cited at p. 10 of DenTek's opening brief on claim construction ("DenTek Br." at 10.)

The Abstract of the '051 invention

The Federal Circuit has indicated that the Abstract of a patent should also be considered to determine the scope of the invention. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F. 3d 1337, 1343 (Fed. Cir. 2001); *Pourchez v. Diatek, Inc.*, 265 F. Supp. 2d 192, 197 (S.D.N.Y. 2003).

The Examiner's Reasons for Allowance

37 C.F.R. §1.104(e) provides that an examiner may provide a reason for allowance of the claims if the examiner believes that the record of the prosecution as a whole does not make clear his or her reasons for allowing the claims. The Manual of Patent Examining Procedure ("MPEP") §1302.14 (8th ed. 2001 (Latest Revision August 2006)) advises that this information "facilitates evaluation of the scope and strength of a patent by the patentee and the public and may help avoid or simplify litigation of a patent." This comports with the policy of providing a competitor fair notice from the prosecution history as to the scope of the claim so that he may conduct his affairs with knowledge where he may tread without trespassing. *Hoganas AB v. Dresser Indus.*, 9 F.3d 948 (Fed. Cir. 1993); *Haynes Int'l v. Jessop Steel Co.*, 8 F.3d 1573, 1578 (Fed. Cir. 1993) ("The legal standard for determining what subject matter was relinquished is an objective one, measured from the vantage point of what a competitor was reasonably entitled to conclude, from the prosecution history, that the applicant gave up to procure issuance of the patent.")

The weight of Federal Circuit precedent establishes the importance of the Reasons For Allowance in construing the claims. *See Koepnick Med. & Educ. Research Found. v. Alcon Labs.*, 162 Fed. Appx. 967, 972 (Fed. Cir. 2005) ("The prosecution history further confirms the district court's construction of 'excising' as 'cutting out.' The PTO examiner asserted in the Notice of Allowance of the '303 patent that 'the primary reason for allowance is that the prior art of record fails to teach or adequately disclose the steps of cutting two disks from the eye.' Koepnick did not challenge the examiner's characterization of its invention." (internal citations omitted)); *ACCO Brands, Inc. v. Micro Sec. Devices, Inc.*, 346 F.3d 1075, 1079 (Fed. Cir. 2003); *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999).

While a failure on the part of an applicant to dispute an Examiner's Reasons For Allowance of a patent claim may not always work an absolute estoppel against a broader interpretation, what was said is always relevant to claim construction. *See Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1347 (Fed. Cir. 2005). Furthermore, to the extent the Examiner characterizes the invention by reference to what the prior art failed to show, the Examiner's Reasons For Allowance will generally work an estoppel against the patentholder's attempts to advance a broader construction. *See Koepnick Med etc., supra*; *Cytyc Corp. v. TriPath Imaging, Inc.*, 2005 U.S. Dist. LEXIS 29850 at *30, n.8 (D. Mass. Nov. 28, 2005) (Finding the patentee estopped to argue that the claim covered one image because: "Here, the examiner did not approve the *182* patent based on a narrow definition of 'image'. The examiner approved the *182* patent because it contained a second image, where the prior art contained only one.")

B. The Accused Product and Statements to the FDA Under Section 510(k) Are Not Relevant To Claim Construction

Claim construction is directed to determining the meaning of the patent from its text, the prosecution history and prior art of record. Extrinsic evidence, such as expert testimony, may

bear on the proper construction. However, the structure of the accused product, developed long after the patent was filed, is not relevant to construing the claim. *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1330 (Fed. Cir. 2006) ("This court, of course, repeats its rule that 'claims may not be construed with reference to the accused device.'"). Medtech points to DenTek's submission to the Food and Drug Administration ("FDA"), as well as some incorrect test data it purports to have on the accused device. (Medtech Br. at 3.) However, the DenTek 510(k) compares the accused product, the DenTek NightGuard, with Medtech's commercial embodiment, the Doctor's NightGuard, and not the narrow improvement stated in the claims. Nothing is said about the patent and reference to Medtech's product, like DenTek's, is irrelevant. *Clintec Nutrition Co. v. Baxa Corp.*, 988 F. Supp. 1109, 1116 (N.D. Ill. 1997) ("It is error for a court to compare in its infringement analysis the accused product . . . with the patentee's commercial embodiment.").

ARGUMENT

Following the exchange of initial claim construction briefs, the parties have jointly agreed upon several definitions and will file a stipulation shortly[1]. The following section discusses only those terms still in dispute.

I. AN INTEROCCLUSAL APPLIANCE

Term or Phrase to be Construed	DenTek's Construction	Medtech's Revised Construction
an interocclusal appliance	a device that prevents full occlusion of all teeth	an appliance or device that is used or fitted, in whole or in part, between portions of the upper and lower teeth[2]

[1] Remaining terms have been firmly agreed upon except for "resin." DenTek is prepared to accept the definition of resin that Medtech proposed as a compromise (Medtech Br. at 15). Since then, Medtech has backed away from this definition and has proposed "any of a number of substances or compounds that are solid or semi-solid after molding and may be thermoplastic or thermosetting", which would encompass plaster of Paris and concrete, and is plainly incorrect.

[2] Medtech revised its construction of this term by adding the words "or device" in its initial claim construction brief.

Medtech's construction is directly contrary to the description contained in the '051 Patent insofar as it claims that the device may be fitted "in part" between "portions of" the upper and lower teeth. The '051 Patent only describes an appliance having a base in the general shape of the maxillary dental arch (something defined by all of the user's teeth) and an impression preform, molded along the entire upper surface of the base, that is "transformed into a maxillary dentition encasement during self-fitting of the interocclusal appliance." (Col. 2, ll. 18-21; Col. 3 at ll. 59-66; Col. 4, ll. 46-60; Abstract.) There is not the slightest suggestion that some portion of that would suffice and serve the purpose of preventing damage from clenching or grinding. A stated objective of the '051 patent is the prevention of tooth structure loss (col. 3 at ll. 6-9), and a proper interpretation would be "consonant with the purpose of the invention." *Hockerson-Halberstadt*, 222 F.3d at 956. DenTek's definition is consistent, by preventing full occlusion. Medtech's is not.

II. MOLDING OVER THE BASE

Term or Phrase to be Construed	DenTek's Construction	Medtech's Revised Construction
molding over the base	contacting a heated resin with the entire upper surface of the appliance base	the step of forming or shaping the impression preform of the appliance on the appliance base

In revising its construction from the original construction reproduced below in footnote 3[3], Medtech attempts to step back from the implications of its choice to use the word "over" in claim 17, a term that clearly conveys the impression preform is molded over the entire upper surface of the base. At col. 4, ll. 46-50, the patent expressly states that when the preform is "molded over the base," **all** of the upper surface of the base and the opposed inner side walls of 18, 20 are bonded to the impression preform 14. The '051 patent makes it clear that the top surface of the base serves as the mold to which the bottom of the preform impression conforms

[3] "Plaintiff defines this term as 'a step of molding over the base.'" (Medtech Br. at 17.)

and bonds. ('051 patent, col. 5, ll. 6-12.) In every single example, the copolymer used to form the impression preform is injection molded into the occlusal appliance mold cavity that contains the molded base, such that the heated copolymer is molded **over** the molded base to form a unitary appliance. (*See, e.g.*, '051 patent, col. 5, ll. 33-56, emphasis added.) In its construction of the term "impression preform," discussed *infra*, Medtech even itself states that the impression preform is "a formable material **overlying** the base." (Medtech Br. at 18, emphasis added.)

The Summary of the Invention is also completely clear on the point, characterizing the invention as follows:

> Molded **into the base between and above the side walls** is an impression preform comprising an EVA copolymer having approximately thirty percent vinyl acetate…. (Col. 2, ll. 3-4, emphasis added.)

The specific placement of the impression preform over the base, including the surfaces of its side walls, is consistent with the purpose of overcoming problems with durability of the appliance. As a result of being bonded to those walls as well as the entire top surface of the base, the impression preform is stabilized against shear forces that had previously led to separation of the impression preform from the base and a lack of durability. (Col. 1 at ll. 43-45 and 54-57; col. 10, ll. 39-44.) The inventors stated their intent to provide an interocclusal appliance characterized by a high shear resistance bond. (Col. 3, ll. 1-5.) This too, then, supports DenTek's construction. *Hockerson-Halberstadt, Inc., supra.*

The Statement of the Invention, the Abstract, every mention of the subject throughout the specification, and the Examiner's stated Reasons For Allowance are in absolute harmony in supporting DenTek's construction. *Microsoft,* 357 F.3d at 1348. So is the dictionary. (Sieczk. Decl. at Ex. C.) Seen for what it really is, Medtech's revised construction is an impermissible attempt to rewrite clear claim language from what it is into what Medtech wishes it might be. *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("in accord with our

settled practice we construe the claim as written, not as the patentees wish they had written it.")

III. AN IMPRESSION PREFORM

Term or Phrase to be Construed	DenTek's Construction	Medtech's Construction
an impression preform	a hardened resin structure containing a channel with curving sides and a flat bottom, and a footing that extends from a horizontal upper surface of the base to the channel face	a formable material overlying the base

Medtech's definition fails to conform to what the patent says is the invention. As developed above, the problem was improper fitting and the solution was an impression preform with side walls defining a channel to guide the user. The Summary of the Invention sets out the importance of the structure of the impression preform to proper fitting:

> The appliance is thereafter inserted in the oral cavity with the centric relation pilot channel substantially registered with the teeth of the maxillary arch. Light pressure is applied to seat the maxillary occlusal surfaces in the shallow preform pilot channel, after which biting pressure is applied to imbed the maxillary teeth in the preform footing. (*See* '051 patent at Col. 2, ll. 18-25.)

This pilot channel solved a major deficiency identified by the patent, the inability to center and align the impression preform relative to the user's maxillary arch. In the Abstract, this channel is termed a "positioning channel," which is indicative of its function in bringing the user's teeth into alignment with the curving sides and a flat bottom of the impression preform.

Medtech criticizes the definition of "impression preform" supplied by DenTek as improper in that it seeks to import the limitations of Claim 1 into Claim 17. (Medtech Br. at 18.) To the contrary, DenTek has construed the term "impression preform" to be consistent with the specification and the PTO Examiner's Reason For Allowance.[4] *See ACCO Brands, Inc.*, 346

[4] Those Reasons For Allowance read, in pertinent part,… [t]he prior art does not disclose or suggest in [sic] interocclusal appliance having a base… [an] impression material bonded to the base, the impression material has a pilot channel having a generally planar face and a pair of space [sic] peripheral walls, the impression material has a footing having a height extending

F.3d at 1079 ("We conclude that the pin clause of claim 10 must be construed in the same way as the pin clause of claim 1, for the examiner's Reasons for Allowance make clear that the examiner and the applicant understood that the invention requires that the pin extends (actively) into the slot after rotation.") The impression preform is a hardened resin structure that may be softened to conform to the shape of the maxillary dentition and encase it during self-fitting. (DenTek Br. at 22) (*See* '051 patent at Col. 3, ll. 64-67; and Col. 4, ll. 55-58.) That definition or DenTek's original definition are each accurate. Every example in the specification, as well as the Reasons For Allowance, consistently point to such a definition. *Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1301-02 (Fed. Cir. 2004).

IV. HAVING APPROXIMATELY 30% BY WEIGHT VINYL ACETATE

Term or Phrase to be Construed	DenTek's Construction	Medtech's Revised Construction
having approximately 30% by weight vinyl acetate.	having at least 25.0% by weight vinyl acetate but not more than 33.0% by weight vinyl acetate	having about, roughly, or around 30% by weight vinyl acetate

Medtech would muddy the waters by defining the term "approximately" with equally murky terms such as "about, roughly, or around." (Medtech Br. at 20.) This adds nothing for a jury. Both dictionaries and judicial decisions have found the terms "about" and "approximately" to be synonyms. *See generally* Dilworth, *About 'about' and Other Imprecise Claim Terms*, 78 J. Pat. & Trademark Off. Soc'y 423 (1996).

DenTek states in its claim construction brief that "having approximately 30% by weight vinyl acetate" means "having at least 25.0% by weight vinyl acetate but not more than 33.0% by weight vinyl acetate." This precise range is directly derived from the '051 Patent, which sets the absolute minimum vinyl acetate (VA) content at 25% by weight ('051 Patent at Col. 5, ll. 13-16), and also discloses a single EVA-containing resin, ELVAX®150, which is claimed in the '051

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from the opposite face of the base to the face of the pilot channel, the height of the footing being at least twice the distance between the occlusal face of the base and the opposite face of the base.

patent to be 33% VA by weight (*e.g.*, '051 patent, col. 5, ll. 13-17.) Clearly, a VA content below 25% would not be "approximately 30%", but would instead be closer to, and therefore more properly termed, "approximately 20%," which is not present in the specification. For the same reason, the upper range of VA content cannot approach 40%. More to the point, the Summary of Invention and claims do not claim approximately 33% but rather approximately 30%. There is no suggestion anywhere in the patent that approximately 30% may exceed 33% on the upside.

Medtech's assertion that there is a vinyl acetate concentration in the DenTek nightguard which is 34.3% by weight (Medtech Br. at 21) is factually incorrect and legally irrelevant. *Wilson Sporting Goods Co., supra*. Where, as here, the claims and the specification of the '051 Patent fail to suggest any range other than that propounded by DenTek, the percentages stated in the body of the patent are the only appropriate guide for defining the boundary of the claim in accordance with the requirements of the second paragraph of 35 U.S.C. § 112.

CONCLUSION

For all the foregoing reasons and the reasons set forth in DenTek's Memorandum on Claim Construction of Claim 17 of the '051 Patent, DenTek respectfully requests that each of its proposed constructions be adopted.

Dated: July 20, 2007

PROSKAUER ROSE LLP

By: s/ Alan Federbush

James H. Shalek
Alan Federbush
1585 Broadway
New York, New York 10036-8299
(212) 969-3000 (phone)
(212) 969-2900 (fax)

Attorneys for Defendant
DenTek Oral Care, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2007, I caused a true and correct copy of the **REPLY OF DEFENDANT DENTEK ORAL CARE, INC. TO PLAINTIFF MEDTECH PRODUCTS INC.'S CLAIM CONSTRUCTION BRIEF** to be served upon the following parties, unless otherwise noted, by use of the Court's ECF system:

Attorneys for Plaintiff Medtech Products, Inc.:

Karl Geercken
Amy Manning
ALSTON & BIRD LLP
90 Park Avenue
New York, NY 10016

AND

W. Edward Ramage (BY E-MAIL)
BAKER, DONELSON, BEARMAN
CALDWELL & BERKOWITZ, P.C.
Commerce Center, Suite 1000
211 Commerce Street
Nashville, TN 37201

Attorneys for Consolidated Defendant Power Products, Inc.:

Kathy Dutton Helmer
Anthony P. La Rocco
Kirkpatrick & Lockhart Preston Gates Ellis, LLP
One Newark Center, 10th Floor
Newark, NJ 07102

s/ Alan Federbush
Alan Federbush